# Q&A: The Contact Lens Rule and the Eyeglass Rule

Federal Trade Commission ■ Bureau of Consumer Protection ■ Office of Consumer and Business Education

#### Introduction

The Federal Trade Commission enforces both the Contact Lens Rule and the Eyeglass Rule. Both Rules require that eye care providers give their customers copies of their prescriptions. Contact lens prescriptions must be given to the customers once the lens fitting is complete; eyeglass prescriptions must be given to customers at the end of the eye exam. The following questions and answers were written to help eye care providers comply with the Rules. If you're an eye care provider or seller with additional questions about the Rules, please call 202-326-3528.

If you're a consumer who thinks that your eye care provider didn't give you a copy of your prescription after your last eye exam or completed contact lens fitting, you may want to remind them about the Eyeglass Rule and the Contact Lens Rule. In addition, you can file a complaint with the FTC at www.ftc.gov. You also may want to contact your state consumer protection agency if your state law also requires your eye care provider to give you your prescriptions.

#### Who — and What — the Rule Covers

- Q: I'm an optician. Am I considered a "prescriber" under the Contact Lens Rule?
- A: Under the Contact Lens Rule, opticians are prescribers if state law permits them to fit contact lenses and to issue prescriptions. Sometimes these prescribers are called "dispensing opticians."
- Q: I'm a prescriber. What is my liability if I verify a prescription and then something is wrong with the contact lenses the consumer bought from another seller?
- A: The Fairness to Contact Lens Consumers Act and the Contact Lens Rule don't impose liability on a prescriber for problems with contact lenses sold by another seller. Traditionally, state law determines the resolution of such issues.
- Q: I'm a prescriber. If I don't act on a verification request, the prescription is verified passively and the consumer can get the contacts from another seller. Am I liable if something goes wrong with the contact lenses?
- A: Neither the Act nor the Rule impose liability on a prescriber for problems with contact lenses. If problems arise, state law determines who would be liable.
- Q: I'm a prescriber. What if I'm unable to verify my patient's prescription during the eight business hour period, and later on learn that the prescription was inaccurate, expired or invalid? Am I required to contact the seller?
- A: Neither the Act nor the Rule address this situation. State law may address this issue. It would be in the best interest of your patient to contact the seller and the patient to alert them to a possible error in the prescription.

#### Q: Does the Contact Lens Rule apply to contact lens sellers located outside the United States?

A: The Contact Lens Rule applies to all sellers — located inside or outside the U.S. — who provide contact lenses to consumers who live in the U.S.

### Q: Does the Contact Lens Rule apply to non-corrective "cosmetic" or "decorative" contact lenses?

A: If state or federal law requires a prescription to buy cosmetic or decorative contact lenses, prescribers and sellers are required to comply with the Rule.

#### **The Prescription**

#### Q: When do I need to give my patients their contact lens prescriptions?

A: You must give the patient a copy of their contact lens prescription when the lens fitting is complete. Some patients may require follow-up visits after the initial exam and before their contact lens fitting is complete. All follow-up exams must be medically necessary, and eye care providers should use sound professional judgment — based on appropriate and objective standards of care — to make that judgment.

### Q: What if my patient asks for a copy of the contact lens prescription before the lens fitting is complete?

A: The Act and the Rule do not require you to provide the contact lens prescription to the patient before the contact lens fitting is complete. If you are prepared to sell them contact lenses, however, you cannot refuse to give them a copy of their prescription on the grounds that their fitting isn't complete. If you're willing to sell them the lenses, their fitting is complete and you must give them a copy of the prescription.

### Q: In my state, a contact lens prescription expires two years after it is written. Does the Contact Lens Rule change that?

A: No. Under the Act and the Rule, if state law specifies an expiration date of <u>one year or more</u> from the prescription's issue date, the prescription expires on that date.

If state law specifies an expiration date of <u>less than one year</u> from the prescription's issue date, however, the prescription expires on a date determined by the Rule. Specifically, under the Rule, a prescription expires one year from its issue date, unless there is a legitimate medical reason for setting a shorter expiration date.

## Q: The law of my state says I have to provide contact lens prescriptions to patients only if they ask for them. But the Contact Lens Rule says I have to provide the prescriptions regardless. Which law applies?

A: The Contact Lens Rule applies. You must give your patients their contact lens prescriptions at the completion of the contact lens fitting — whether or not the patients ask for them.

### Q: As an eye care provider, can I charge a patient for trial lenses, or require a patient to purchase them?

A: You may but <u>only</u> if the trial lenses are necessary to complete the fitting process. This is sometimes the case with some "specialty" or custom-made lenses. You may not otherwise require a patient to buy contact lenses — such as a six-month supply of disposable lenses — as a condition of giving them a copy of their prescription.

### Q: I'm a contact lens seller. Can I substitute one brand of contact lenses for another brand under the Rule?

- A: You can substitute one brand of contact lenses for another if:
  - the prescription specifies private label lenses and
  - the substitute lenses are identical to the prescribed lenses.

Example: TekViz, Inc. manufactures and sells the exact same contact lenses under both the "TekViz" brand and the "Dr. Jones" brand. If the prescription specifies "Dr. Jones" brand lenses, the seller may substitute "TekViz" brand lenses. The seller may not substitute non-identical lenses manufactured by TekViz, Inc. or lenses manufactured by a different contact lens manufacturing company.

- Q: The Contact Lens Rule says prescribers must provide or verify contact lens prescription information "as directed" by a third party designated by a patient. But according to HIPAA, don't I have to get written authorization from a patient before providing or verifying his contact lens prescription to a seller?
- A: No. HIPAA (Health Insurance Portability and Accountability Act of 1996) permits covered entities to use or disclose protected health information without patient authorization if the use or disclosure is for "treatment" or "required by law." Providing, confirming, correcting, or verifying a contact lens prescription to a seller designated by the patient constitutes treatment or is required by the Act and the Rule.

### Q: As the eye care provider, may I include a specific number of refills on a contact lens prescription?

A: The Contact Lens Rule doesn't require or prohibit you from including refill quantities on contact lens prescriptions. If your state law requires such information — or prohibits it — follow your state law.

In either case, however, the Rule does <u>not</u> allow you to use refill quantities to shorten a prescription expiration period to less than one year, unless there are legitimate medical reasons for doing so.

#### **Record-keeping Requirements for Sellers**

Q: As a contact lens seller, I've called a lot of eye care providers to find out whether they have Saturday business hours. What records do I have to keep to show I have "actual knowledge" of their Saturday business hours?

A: As a seller, you must keep a record of the eye care provider's regular Saturday hours and how you know those are the hours. If you call eye care providers to learn their actual business hours, keep a list of your notes from those calls for record-keeping purposes, as long as your notes reflect the necessary information. Remember that you must include Saturday business hours on a verification request if you want to include those hours in the "eight-business-hour" verification period.

### Q: Can my verification request form state that I assume that all prescribers' offices have Saturday business hours unless the prescriber's office tells me otherwise?

A: No. A seller may only count a prescriber's Saturday business hours as part of the "eight-business-hour" verification period if the seller has <u>actual knowledge</u> that the prescriber has Saturday business hours. Assuming that a prescriber has Saturday business hours unless the prescriber tells you otherwise does not constitute actual knowledge under the Rule.

### Q: As a seller, can I depend on information given to me by a customer about an eye care provider's Saturday business hours?

A: Depending on the circumstances, information you get from a consumer also may be acceptable under the Rule. For example, if a consumer gives you the prescriber's business card, which states that their office is open from 9 a.m. to 3 p.m. on Saturdays, you may rely on it. Remember to document that this information is the basis for your Saturday hours determination.

### Q: What if the customer tells me, "I think my eye doctor's office is open from 9 a.m. to 5 p.m. on Saturdays"?

A: You may not rely on a customer's statement alone as a basis for your actual knowledge of a prescriber's regular Saturday hours. You should verify an eye care provider's Saturday hours some other way.

#### "Eight-business-hours" for Verification

#### Q: I'm a prescriber. How long do I get to verify a prescription?

A: The Act and the Rule give prescribers "eight-business-hours" to verify a prescription. A "business hour" is an hour during the period from 9 a.m. to 5 p.m. Monday through Friday (excluding federal holidays), plus hours on Saturdays that the seller actually knows the prescriber is regularly open for business. Business hours are calculated based on the prescriber's time zone.

### Q: How is the "eight-business-hour" period calculated if the seller's verification request is received during business hours?

A: If the verification request is received during business hours, the "eight-business-hour" period starts when the prescriber receives the request from the seller and ends when "eight-business-hours" have elapsed.

Say the verification request is received at 4 p.m. on Monday. The "eight-business-hour" period would begin at 4 p.m. on Monday and end at 4 p.m. on Tuesday. If the eye care provider doesn't respond, the seller can ship at 4:01 p.m. on Tuesday.

Say the verification request is received at 11 a.m. on Friday. The seller has documented actual knowledge that the eye care provider's office is regularly open from 10 a.m. to 4 p.m. on Saturdays. In this case, the "eight-business-hour" period would begin at 11 a.m. on Friday and end at noon on Saturday. If the eye care provider doesn't respond, the seller can ship at 12:01 p.m. on Saturday.

Suppose you get a verification request at 11 a.m. on Friday, but the eye care provider's office isn't regularly open on Saturdays. The "eight-business-hour" period would begin at 11 a.m. on Friday and would end at 11 a.m. on Monday. If the eye care provider doesn't respond, the seller can ship at 11:01 a.m. on Monday.

Or suppose you get a verification request at 2 p.m. on Monday, and the next day is Christmas. The "eight-business-hour" period would begin at 2 p.m. on Monday and would end at 2 p.m. on Wednesday. If the eye care provider doesn't respond, the seller can ship at 2:01 p.m. on Wednesday.

### Q: How is the "eight-business-hour" period calculated if the seller's verification request is received outside business hours?

A: If the verification request is received outside of business hours, the "eight-business-hour" period starts at 9 a.m. on the next weekday that isn't a federal holiday (or, if applicable, on Saturday at the start of the prescriber's actual regular business hours) and ends "eight-business-hours" later.

For example, the verification request is received at 7 p.m. on a Tuesday. The "eight-business-hour" period would begin at 9 a.m. on Wednesday and would end at 5 p.m. the same day. If the eye care provider doesn't respond, the seller can ship at 5:01 p.m. on Wednesday.

Or, the verification request is received at 2 p.m. on a Saturday. The eye care provider's office is not regularly open on Saturdays, and Monday is July 4. The "eight-business-hour" period would begin at 9 a.m. on Tuesday and would end at 5 p.m. on Tuesday. If the eye care provider doesn't respond, the seller can ship at 5:01 p.m. on Tuesday.

#### **Direct Communication**

#### Q: When is a direct communication "completed" under the Contact Lens Rule?

A: A direct communication is completed when the recipient gets all the required information. For example, direct communication by telephone requires reaching and speaking with the intended recipient, or leaving a clear voice message including all the required information on the recipient's telephone answering machine. Similarly, direct communication by fax or email requires that the intended recipient receive the fax or email message.

#### Q: How do I know that a direct communication by fax or email has been completed?

A: A fax confirmation sheet showing that a fax was transmitted usually is sufficient to conclude that the received the fax.

Confirmation that an email was sent generally is sufficient to conclude that it was received. Of course, if the sender has reason to believe that an email message was not transmitted instantly (such as receiving an electronic notice stating that the email could not be sent), the communication is not considered completed until it is actually received by the recipient.

### Q: My company sells contact lenses to consumers. Can I use an automated telephone system to send a verification request to an eye care provider?

- A: As long as the request fully complies with the Rule: The verification request must provide all the information required, and you must wait "eight-business-hours" (to allow the eye care provider to respond to the request) before you sell contact lenses to the consumer.

  For example, an automated telephone system that leaves a voicemail message containing incomplete verification information does not comply with the Rule. Similarly, an automated telephone system that requires the prescriber's office to provide an immediate response does not comply with the Rule.
- Q: I'm a seller who uses the telephone for direct communication with eye care providers. Do I have to keep a written log of all communications, or can I store this information electronically?
- A: The Rule allows you to store the information electronically, provided all the required information is contained in the electronic records, and the information can be made available for review by the Commission, if necessary.